

FEB 2 2006

**510(k) Summary** (Prepared on December 30, 2005)

This 510(k) Summary is submitted in accordance with 21 CFR 807.92.

<b>Trade Names:</b>	Aquadex FlexFlow™ System (trademark pending)	
<b>Manufacturer:</b>	CHF Solutions, Inc., Suite 170 - 7601 Northland Drive, Brooklyn Park, MN 55428	
<b>Official Contact:</b>	Chris Scavotto QA Manager	Telephone: 763-463-4621 Fax: 763-463-4606
<b>Device Generic Name:</b>	Ultrafiltration (Aquapheresis) System	
<b>Classification:</b>	High permeability dialysis systems - classified as Class II	
<b>Predicate Devices:</b>	Aquadex FlexFlow System (K050609)	Hemametrics Blood Chamber and Blood Chamber tubing adaptor set CRIT-LINE III TQA Monitor (K982412 & K011741)
<b>Device Description:</b>	The Aquadex FlexFlow System removes excess fluid from the patient in fluid overload by ultrafiltration of blood across a hollow-fiber hemofilter at the clinician selected rate. The system is comprised on a console mounted on a cart, proprietary software and accessories (venous access catheters, extensions and a blood pump circuit). Patient access is obtained via either peripheral or central venous veins. This 510(k) is to add an alternate blood pump circuit which has a standard male and female luer adapter just before the filter on the withdrawal line to allow the optional use of a blood chamber cuvette to interface with a stand alone Hct monitor.	
<b>Indication for Use:</b>	The Aquadex FlexFlow™ System is indicated for: <ul style="list-style-type: none"><li>• Temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and</li><li>• Extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.</li></ul> All treatments must be administered by a health care provider, under physician prescription, both of whom having received training in extracorporeal therapies.	
<b>Safety &amp; Performance:</b>	Bench tests were performed to validate the incorporation of the blood chamber placement in-line on the withdrawal line of the blood circuit. No software change was required. The data demonstrated the Aquadex FlexFlow System continues to be safe and effective.	
<b>Conclusion:</b>	Based on the similar intended use, patient population, technology characteristics, and performance as assessed with bench testing the alternate UF500 blood circuit (PN A1700) has been shown to be safe and effective, is substantially equivalent <sup>4</sup> and considered acceptable for the intended use.	

<sup>4</sup> This document uses the term "substantial equivalent" as intended in 21 CFR 807.87 and not as defined in Title 36 of the U.S. Code.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 2 2006

Mr. Chris Scavotto  
Quality Assurance Manager  
CHF Solutions, Inc.  
7601 Northland Drive, Suite 170  
BROOKLYN PARK MN 55428

Re: K060008  
Trade/Device Name: Aquadex FlexFlow™ System  
Regulation Number: 21 CFR §876.5860  
Regulation Name: High permeability hemodialysis system  
Regulatory Class: II  
Product Code: KDI  
Dated: December 30, 2005  
Received: January 3, 2006

Dear Mr. Scavotto:

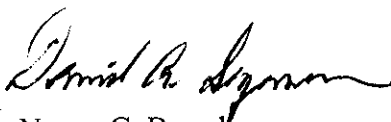
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
for Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**  
(Page 1 of 1)

510(k) Number (if know): K05 K060008

Device Name: Aquadex FlexFlow™ System

**FDA's Statement of the Indication For Use for Device:**

The Aquadex FlexFlow™ System is indicated for:

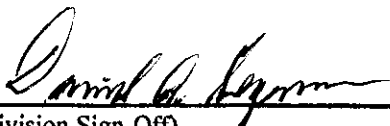
- Temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and
- Extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.

All treatments must be administered by a health care provider, under physician prescription, both of whom having received training in extracorporeal therapies.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K060008

Prescription Use ☒   
(Per 21 CFR 801.109)

OR Over-The-Counter Use ☐